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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,546	09/29/2006	Hyun-Su Bae	53768-10100	1559

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EXAMINER	
CHEN, CATHERYNE	
ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
12/31/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,546	BAE ET AL.	
	Examiner	Art Unit	
	CATHERYNE CHEN	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Currently, Claims 1, 3-12 are pending. Claims 1, 3-12 are examined on the merits.

In view of the Appeal Brief filed on Sept. 23, 2008, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Terry A. McKelvey/

Supervisory Patent Examiner, Art Unit 1655

Response to Arguments

Applicant's arguments, see Appeal Brief, filed Sept. 23, 2008, with respect to Claims 1, 3-12 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the references below.

Claim Objections

Claim 3 is objected to because of the following informalities:

Claim "I" should be "Claim "1."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4 recite the limitation "the hot water" in extraction. There is insufficient antecedent basis for this limitation in the claim. The term "hot water" is not used in the preceding claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Sohn et al. (2003, Phytomedicine, 10, 165-167).

Sohn et al. teaches seeds of N. nucifera extracted with ethanol under reflux for 3 hours and filtrate was evaporated in vacuo (PAGE 166, Plant material and preparation of ENN). N. nucifera is also known as Nelumbinis semen or lotus seed (see http://www.tcmbasics.com/materiamedica/semen_nelumbinis.htm). The process of refluxing requires heating a solution from aqueous to gas phase and ethanol is dissolved in water. Boiling of water in 1 atmospheric pressure requires the temperature to be 100 degree Celsius. Therefore, water is inherently taught by the reference to be heated to 100 degree Celsius.

Claims 1, 3-5, 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Akiyama et al. (JP 63066126 A).

Akiyama et al. teaches a drug from lotus seed embryo bud extracted by water, then concentrated the extract solution by refluxing for 5 hours (Abstract). Lotus seed is also known as Nelumbinis semen (see http://www.tcmbasics.com/materiamedica/semen_nelumbinis.htm). The process of refluxing requires heating a solution from aqueous to gas phase, which requires boiling

water. Boiling of water in 1 atmospheric pressure requires the temperature to be 100 degree Celsius. Therefore, water is inherently taught by the reference to be heated to 100 degree Celsius.

Claims 5-7, 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Lotus Seed (March 2002, http://www.itmonline.org/arts/lotus.htm).

Lotus Seed teaches lotus seed boiled in water and simmered for 1.25 to 1.5 hours or until the beans are tender (page 1, Red Bean and Lotus Seed Soup). Lotus seeds can be used for food and medicine (page 1, paragraph 1; page 2, paragraph 5.) Lotus seed is also known as Nelumbinis Semen (see http://www.tcmbasics.com/materiamedica/semen_nelumbinis.htm). Boiling of water in 1 atmospheric pressure requires the temperature to be 100 degree Celsius.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bae et al. (KR 1020030079104 A).

The claims are drawn to Nelumbinis Semen composition comprising Nelumbinis Semen as the active ingredient, within a product-by-process claim.

Bae et al. teaches a pharmaceutical composition and health food of an extract of Nelumbinis semen for the treatment of depression (Abstract).

The cited reference teaches a composition of 1-100% ethanol or methanol, filtering and concentrating the concentrate, as the active ingredient therein which appears to be identical to (and thus anticipate) the presently claimed extract Nelumbinis Semen composition since the prepared ingredient has similar aqueous extraction, concentration steps, and demonstrate the same/similar activity with respect to treating depression. Consequently, the instantly claimed red vine leaf extract composition appears to be anticipated by the cited reference.

In the alternative, even if the claimed Nelumbinis Semen composition is not identical to the referenced Nelumbinis Semen extract composition with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced Nelumbinis Semen composition is likely to inherently possess the same characteristics of the claimed

Nelumbinis Semen composition particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed Nelumbinis Semen composition would have been obvious to those of ordinary skill in the art within the meaning of USC 103. Further, if not anticipated, the result-effective adjustment of particular conventional working conditions (e.g., for use as pharmaceutical and health food to treat depression) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether the Nelumbinis Semen extracts within Applicant's composition differ and, if so, to what extent, from the levels within the Nelumbinis Semen disclosed by the cited reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Please also note that "the patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although

produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bae et al. (KR 1020030079104 A) in view of Liu (CN 1368022 A) and Sohn et al. (2003, Phytomedicine, 10, 165-167).

Bae et al. teaches a pharmaceutical composition and health food of an extract of Nelumbinis semen for the treatment of depression (Abstract). However, it does not teach water at 80-100 degree Celsius for 1-3 hours and refluxing.

Liu teaches lotus seed's embryonic bud is boiled with purified water and features nutritive components (Abstract). Lotus seed is also known as Nelumbinis Semen (see http://www.tcmbasics.com/materiamedica/semen_nelumbinis.htm). Boiling of water in 1 atmospheric pressure requires the temperature to be 100 degree Celsius.

Sohn et al. teaches seeds of N. nucifera extracted with ethanol under reflux for 3 hours and filtrate was evaporated in vacuo (PAGE 166, Plant material and preparation of ENN). N. nucifera is also known as Nelumbinis semen or lotus seed (see http://www.tcmbasics.com/materiamedica/semen_nelumbinis.htm).

Liu teaches lotus seed's embryonic bud is boiled with purified water and features nutritive components (Abstract). Sohn et al. teaches seeds of N. nucifera extracted with ethanol under reflux for 3 hours and filtrate was evaporated in vacuo (PAGE 166, Plant material and preparation of ENN). Thus, an artisan of ordinary skill would reasonably expect that the process of extracting Nelumbinis semen can be done with water and refluxed for 3 hours could be used as the types of extracts to treat depression taught by the references. This reasonable expectation of success would motivate the artisan to use water extraction and refluxing for extracting Nelumbinis Semen in the reference composition. Thus, using the process of boiling in water by refluxing for 1-3 hours is considered an obvious modification of the references.

The references also do not specifically teach performing the process in the time span and temperature range claimed by applicant. The process in the time span and temperature range is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are

disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal process in the time span and temperature range to use in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Conclusion

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen
Examiner Art Unit 1655

/Michael V. Meller/
Primary Examiner, Art Unit 1655